

Genetic Modification of Stem Cells and T cells to Activate the Immune System to Target Solid Tumors

Grant Award Details

Genetic Modification of Stem Cells and T cells to Activate the Immune System to Target Solid Tumors

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-11380

Project Objective: Complete Phase 1 trial using genetic modification of stem cells and T cells to activate the

immune system to target solid tumors

Investigator:

Name: Theodore Nowicki

Institution: University of California, Los

Angeles

Type: PI

Disease Focus: Cancer, Sarcoma, Solid Tumors

Human Stem Cell Use: Adult Stem Cell

Award Value: \$4,693,839

Status: Active

Grant Application Details

Application Title: Genetic Modification of Stem Cells and T cells to Activate the Immune System to Target Solid

Tumors

Public Abstract:

Therapeutic Candidate or Device

Autologous Peripheral Blood Stem Cells expressing the NY-ESO-1 TCR and a suicide/reporter gene combined with T cells expressing the same TCR

Indication

Locally advanced (unresectable stage IIIc) or metastatic malignancies (stage IV) that are HLA A2.1+, NY-ESO-1+, solid tumors, including sarcomas

Therapeutic Mechanism

The administration of TCR transduced mature lymphocytes will expand in vivo and provide a first wave of transient antitumor activity. This will provide a bridge until the genetically modified CD34+ cells expressing a transgenic NY-ESO-1 TCR give rise to T cells recognizing the NY-ESO-1 antigen presented by HLA-A2*0201 in NY-ESO-1 positive malignant cells generating a renewable source of TCR transduced cells for sustained antitumor activity.

Unmet Medical Need

The rarity of sarcomas limits funding and available treatments. This trial will constitute one of the very few options for patients with relapsed or recurrent sarcoma, who have a high prevalence of NY-ESO-1 tumor expression, as well as other types of solid tumors with high NY-ESO-1 expression.

Project Objective

Phase 1 trial completed

Major Proposed Activities

- Vectors production and assess feasibility of cell product manufacturing
- Assess clinical safety, T cell persistence and anti-tumor response of the combination of the cell products administered
- Assess biodistribution of the modified stem cells and progeny

Statement of Benefit to California:

The clinical success would foster the modification of our current techniques for cell therapy manufacture to be adapted to a larger scale manufacturing procedure compatible with commercialization. This would broaden the impact of this stem cell-based research for patients in California and the US.

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